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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,219	11/17/2003	Manesh Dixit	141-269	4442
47888 7590 02/07/2008 HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 02/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/715,219

Applicant(s)

DIXIT ET AL.

Examiner

Humera N. Sheikh

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

NINETY (90)

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR ~~THIRTY (30)~~ DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/19/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks, all filed 11/13/07 and the Information Disclosure Statement (IDS) filed 11/19/07 is acknowledged.

Upon further review and consideration the previous Restriction/Election requirement filed 04/05/07 has been withdrawn. Previously withdrawn claims 15, 17 and 23-32 are hereby rejoined and are being examined with the remaining elected claims (1-14, 16 & 18-22).

Upon further review and consideration, the previous Non-Final Office Action filed 08/10/07 has been withdrawn. The following are the new grounds of rejection:

Claims 1-32 are pending in this action. Claims 1, 6 and 20 have been amended. Claims 1-32 are being examined in this action. Claims 1-32 are rejected.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the active metabolite, O-desmethylvenlafaxine (ODV), does not reasonably provide enablement for any and all active metabolites of venlafaxine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. A review of the instant specification on pages 1-2 indicates that the only active metabolite of venlafaxine disclosed is ODV active metabolite. No additional active metabolite(s), or analog(s) or isomer(s) are disclosed therein. The only metabolite listed is ODV. Thus, the specification only supports the ODV active metabolite of venlafaxine, but not any and all active metabolites, analogs or isomers thereof.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a controlled release composition having a maximum plasma concentration of venlafaxine obtained in less than four (4) hours, does not reasonably provide enablement for a venlafaxine controlled release composition devoid of the four-hour maximum plasma concentration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. A review of the instant specification on page 4 indicates that no evidence has been provided which would demonstrate that the formulation would not have the particular plasma level claimed (less than 4 hours). The specification only supports the maximum plasma concentration of venlafaxine to be obtained in less than four

hours. The limitations of claim 2 should be incorporated into claim 1 to render the claim enabling.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an inert pellet having a diameter ranging from about 15 to about 60 mesh, does not reasonably provide enablement for an inert pellet having a diameter mesh size other than that being claimed in claim 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. A review of the instant specification on page 6 indicates that the only diameter mesh size provided is a diameter ranging from about 15 to about 60 mesh, such as is claimed in instant claim 6. No additional or varying diameter mesh size ranges have been provided. The specification only supports the diameter mesh size of claim 6. The limitations of claim 6 should be incorporated into claim 1 to render the claim enabling.

* * * * *

Response to Arguments

Applicant's arguments, filed 11/13/07 with respect to claims 1-14, 16 and 18-22 have been considered but are moot in view of the new ground(s) of rejection.

* * * * *

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit 1618

February 01, 2008


HUMERA N. SHEIKH
PRIMARY EXAMINER

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